

Supporting Statement A for

Rapid Throughput Standardized Evaluation of
Transmissible Risk for Substance Use Disorder in Youth
(NIDA)

August 1, 2014

Name: Harold Perl, PhD
Chief, Prevention Research Branch,
Division of Epidemiology, Services & Prevention Research,
National Institute on Drug Abuse,
6001 Executive Blvd., Room 5163, MSC 9589,
Bethesda, MD 20892-9589
Telephone: 301-443-1942
Fax: 301-443-2636
Email: hperl@nida.nih.gov

Table of Contents

A. JUSTIFICATION.....4

A.1 CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY.....4

A.2 PURPOSE AND USE OF THE INFORMATION COLLECTION.....7

A.3 USE OF INFORMATION TECHNOLOGY AND BURDEN REDUCTION.....7

A.4 EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION.....8

A.5 IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES.....8

A.6 CONSEQUENCES OF COLLECTING THE INFORMATION LESS FREQUENTLY.....9

A.7 SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINES OF 5 CFR 1320.5.....9

A.8 COMMENTS IN RESPONSE TO THE FEDERAL REGISTER NOTICE AND EFFORTS
TO CONSULT OUTSIDE AGENCY.....9

A.9 EXPLANATION OF ANY PAYMENT OF GIFT TO RESPONDENTS.....11

A.10 ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS.....14

A.11 JUSTIFICATION FOR SENSITIVE QUESTIONS.....16

A.12 ESTIMATES OF HOUR BURDEN INCLUDING ANNUALIZED HOURLY COSTS.....18

A.13 ESTIMATE OF OTHER TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR
RECORD
KEEPERS.....21

A.14 ANNUALIZED COST TO THE FEDERAL GOVERNMENT.....21

A.15 EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS.....22

| | | |
|------|---|----|
| A.16 | PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE..... | 22 |
| A.17 | REASON(S) DISPLAY OF OMB EXPIRATION DATE IS INAPPROPRIATE..... | 24 |
| A.18 | EXCEPTIONS TO CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS..... | 24 |

LIST OF ATTACHMENTS

- Attachment 1: IRB Approval (EXACT)
- Attachment 2: IRB Approval (CEDAR, Pittsburgh)
- Attachment 3: IRB Approval (BCSR, Rutgers)
- Attachment 4: Transmissible Liability Index Survey
- Attachment 5: School Recruitment Letter and School Participation Agreement Form
- Attachment 6: Survey Fact Sheet and Parental Consent Form
- Attachment 7: Web Survey Assent Page Text
- Attachment 8: Twins Consent Form (Adult)
- Attachment 9: Twins Consent Form (Parent)
- Attachment 10: Twin Type and D&A Screening Survey
- Attachment 11: Dysregulation Inventory
- Attachment 12: Certificate of Confidentiality
- Attachment 13: Public Comments to 30 Day Notice
- Attachment 14: NIDA Response to Public Comments

A.1 Circumstances Making the Collection of Information Necessary

The National Institute on Drug Abuse (NIDA) a National Institutes of Health (NIH) institute, has contracted with EXACT Sport LLC (EXACT) to finalize the development of the Transmissible Liability Index (TLI). The TLI is a psychometric tool for detecting youth at elevated risk for substance use disorder (SUD). NIDA issued an RFP for research to advance the TLI from a research tool to a practical instrument, which lead to the contract with EXACT.

The TLI, a web-based platform for assessing risk of SUD, is a highly efficient tool both in terms of the limited time commitment required as well as its low cost. The inexpensive and high efficiency of the TLI for identifying youths in need of prevention, and the strong cost-benefits to society for SUD prevention, portend strong demand for use in a variety of populations including family and social services, schools, mental health facilities, and youth protection agencies.

To transform the TLI prototype into a practical instrument, three core tasks remain, for two organizations have been sub-contracted and serve as project co-investigators:

(1) Standardization on a sample (N= \sim 5,000) that is representative of the general population to generate norms that are specific to age, gender and ethnicity (this task is being conducted by the Bloustein Center for Survey Research [BCSR] at Rutgers, The State University of New Jersey);

(2) Construct validity analysis using standard parametric modeling techniques to show that heritability accounts for the major portion of variance on TLI scores. The sample (150 monozygotic and 150 dizygotic twins) will be representative of the same general population characteristics identified above (the Center for Drug Education and Drug Abuse Research [CEDAR] at the University of Pittsburgh is leading the twins construct validity tasks); and

(3) Psychometric analysis of validity and reliability based on the above data (this task is also being led by CEDAR at the University of Pittsburgh).

Validating the TLI will further the mission of NIDA by legitimating the tool for exploring the attitudes and social predictors of addictive behaviors with the intention of reducing or eliminating drug-taking behavior. This research is squarely within NIDA's mission of research on drug abuse and addiction, as well as its focus on ensuring the rapid and effective dissemination and use of the results to significantly improve efforts to stem substance use disorder.

To move the TLI from the research domain to practical use through commercial dissemination, the research and development team ("the R&D team") needs to satisfy professional quality standards consistent with American Psychological Association (APA) regulations. To show validity and efficacy of the instrument, APA requires a normed, representative data sample. Doing this one-time analysis allows the TLI to be legally and ethically administered across the United States.

To satisfy those standards, the R&D team must demonstrate the reliability and internal validity of the TLI against existing standardized psychometric studies for youth populations, ages 14 to 18. Thus, the TLI must be tested with data collected from youth populations, ages 14 to 18, comparable to those in existing studies. Moreover, the R&D team must provide psychometric external validation for the TLI through data collection from sets of monozygotic and dizygotic (i.e., identical and fraternal, respectively) twins. Psychometric analyses are required to show that the TLI performs according to expectations. Accordingly, these analyses will be performed to demonstrate i) construct, ii) discriminative, iii) concurrent, and iv) predictive validity.

The 14-to-18 year old age range was selected because it encompasses the years typically spent in high school, which are known to be the timeframe when substance use is likely to begin and accelerates, often leading to substance abuse disorder.¹ Notably, the peak period for the manifestation of cannabis-use disorder is age 18-19, and the past-year-prevalence for alcohol-use disorder is age 20-22. The TLI is designed to identify the propensity for these and other substance abuse prior to manifestation; as such, collecting data from the high school age group (14-18 years old) is critical to identifying at-risk youths for the purposes of early intervention.

These benefits are congruent with NIDA's research goals. NIDA has the legislative authority to conduct this research through 42 U.S. Code § 6A(III)(15): National Institute on Drug Abuse (§§ 285o: Purpose of Institute).

¹ Substance Abuse and Mental Health Services Administration, *Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings NSDUH Series H-4*, HHS Publication No. (SMA) 12-4713. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012; Johnston, L. D., O'Malley, P. M., Bachman, J. G., & Schulenberg, J. E. (2013). *Monitoring the Future: National survey results on drug use, 1975–2012: Volume I, Secondary school students*. Ann Arbor: Institute for Social Research, The University of Michigan.

A.2 Purpose and Use of the Information Collection

The data will be used by EXACT Sports LLC (“EXACT”) and Center for Education and Drug Abuse Research (“CEDAR Center”) at the University of Pittsburgh to assess the reliability and validity of the TLI, as described in the immediately preceding response, as well as to build a normative database for future use of the TLI to identify youth at-risk for substance abuse disorder. Doing so will facilitate the movement of the TLI from a research tool to practical use, thereby improving NIDA’s ability to fight the onset of drug addiction. This tool can also be used by the NIH as a recommended practice for intramural and extramural research of prevention and early intervention programs to target those children at greatest risk of negative outcomes prior to their engagement in high-risk health behaviors.

A.3 Use of Information Technology and Burden Reduction

All data collection will be conducted electronically using easily accessible web or computer based interfaces. The Computer-Adaptive Test (CAT) version of the TLI was developed to reduce time and subject burden by eliminating the need for subjects to complete all items, based on response to key items. NIH Privacy Act Systems of Record Notice is 09-25-0200 entitled Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD applies, and a Privacy Impact Assessment is in-process.

A.4 Efforts to Identify Duplication and Use of Similar Information

As this is a new index there are no prior data against which to benchmark and standardize the index.

A.5 Impact on Small Businesses or Other Small Entities

No small business or other small entities will be affected by this study. Rather, this project requests the cooperation of school districts; the protocol minimizes the burden of school teachers and administrators by (1) BCSR's conducting the class-level sample selection, from the school's class list, of which classes should participate; (2) the sample represents a small proportion of the school population; and (3) BCSR provides a web-based data entry tool for the schools to deploy during the data entry process, thus obviating the need for paper-based instrumentation. BCSR has extensive experience in facilitating this type of data collection effort, and will have full-time staff members dedicated to ensuring the minimization of participant burden. Copies of the School Recruitment Letter and School Participation Agreement Form may be found as Attachment 5.

A.6 Consequences of Collecting the Information Less Frequently

Drug abuse is still a significant problem in this country. NIDA strongly believes that by identifying at-risk populations in the ages before drug use becomes prevalent, intervention strategies can be designed to prevent or reduce drug use disorder.² Research shows that if targeted properly to those youth most at risk interventions can reduce drug addiction. In order for these interventions to be effective however, good data on at-risk youth is necessary. This collection is intended to be part of an effort to improve such targeting, and is consistent with the NIH's mission of the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances. This data collection fully complies with 5 C.F.R. 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult

Outside Agency

The 60-day Federal Register Notice, required by 5 CFR 1320.8 (d) to solicit comments on the information collection prior to submission to the OMB, was published on December 3,

² *Preventing Drug Use among Children and Adolescents, A Research-Based Guide for Parents, Educators, and Community Leaders, 2nd Ed.*, (2003). National Institute on Drug Abuse. NIH Pub. Number: 04-4212(A).

2013, in the Federal Register (Vol. 78, No. 232, pgs. 72682 - 72683). One comment was received requesting the draft instruments, which were provided. The 30-day Federal Register Notice was published on March 10, 2014, in the Federal Register (Vol. 79, No. 46, pgs.13317-13318). One comment was received suggesting changes to the Standardized Instrument, and was responded to. These are in Attachment 13 and 14.

The following individuals were consulted on statistical aspects and data collection and analysis aspects of this project:

Center for Education and Drug Abuse Research (CEDAR); University of Pittsburgh:

Levent Kirisci 412-864-2461

Maureen Reynolds 412-488-5006

Michael Vanyukov 412-864-2458

EXACT Sport LLC (EXACT):

Barry Tarter 312-854-2352

Simon Clements 312-854-2356

Bloustein Center for Survey Research (BCSR); Edward J. Bloustein School of Planning and Public Policy, Rutgers, The State University of New Jersey:

| | |
|---------------------|--------------|
| Christopher Bruzios | 848-932-2778 |
| Marc Weiner | 848-932-2765 |
| Timothy Mackinnon | 848-932-2775 |
| Siobhan Foley | 848-932-2782 |
| Orin Puniello | 848-932-2767 |

A.9 Explanation of Any Payment of Gift to Respondents

In this project, two separate incentives are provided: (a) the standardization sample (5000 subjects participating through schools) and (b) the validation sample (600 mono/dizygotic twins). The school incentive is \$500 per school which will be provided to each of the 36 randomly selected participating high schools (total incentives \$18,000). For schools, the incentive will be paid upon the school's facilitation of their students' participation in the study. Separately, in the twins validation sample (not related to the school study), individual participating monozygotic or dizygotic twins will each receive a \$10 incentive for completion of the surveys (total incentives \$6,000). The incentive will be provided on completion of the survey. For each sample, the use of incentives was determined necessary to ensure that subjects were fairly compensated for their participation as well as to facilitate recruitment and ensure effectiveness of the project. First, in terms of the school standardization sample (5000 participants), BCSR's (Rutgers) experience with years of prior similar data collection with the CDC in similar school outreach, such as the Youth Risk Behavior Survey (OMB No. 0920-0493, Expiration 11/30/2011) and the New Jersey Student Health Survey has shown that school-level incentives are an effective and efficient mechanism for securing cooperation and support from sampled schools. Similarly, in other

studies such as “A Controlled Evaluation of Expect Respect Support Groups (ERSG): Preventing and Interrupting Teen Dating Violence among At-Risk Middle and High School Students” (OMB No.0920-0861, Expiration 8/31/2013) and “National Youth Tobacco Survey (NYTS) in 2009 and 2011” (OMB No. 0920-0621, Expiration 01/31/2015), school incentives were offered. In this study, the use of incentives was determined necessary because:

(1) Incentives facilitate a favorable cost/benefit determination by districts and schools as to whether to participate in the research effort.

Elementary and secondary schools are increasingly approached by various researchers and community groups to participate in studies involving the student population. Typically, school district administrators and school principals balance the cost/benefit of each request in order to weigh the importance and relevance of the study, and in turn, determine the willingness of the district and/or school to participate in some or all of these research efforts. Frequently, these requests source to a local, community, regional or statewide initiative for which schools see the direct benefit of their participation. In this study, however, as with the other OMB studies cited below where school-level incentives have been used, the research benefits are to the broader population and/or service providers, as opposed to a direct community-based benefit to the school. As discussed herein, the goal of this effort is to provide data for the creation of a normative database for a predictive instrument to be used by professionals to assess the predisposition of youth to engage in substance use behavior. While the development of this tool is important to NIDA’s mission, as well as more broadly to the field of alcohol and drug abuse prevention, the direct benefit to decision makers at the school level is less evident.

Hence, when weighing the multiple requests for school participation, this effort may not rank in the district/school cost/benefit analysis as highly, when compared to other studies that

provide more direct benefits. The \$500 incentive provides some tangible benefit to schools in that decision making process, and the incentive amount underscores the seriousness of purpose of the study, i.e., the critical importance of the early detection of, and intervention in, the propensity to abuse drugs and alcohol.

(2) Overall research costs are minimized by the use of incentives, because the recruitment period is shorter and the number of research FTE hours necessary to advance the project is minimized.

If all 36 schools participate, the \$500 per school incentive aggregates to \$18,000; however, if no incentives were offered, years of experience in the field, as well as the below cited OMB-approved incentive-based studies, compel that the overall project costs would substantially increase. This is due to the simple logic of sampling, i.e., without the incentive, many more potential-participant schools will need to be contacted to obtain the 36 schools necessary for the study. Thus, with no incentive, many more hours for personnel and research staff would be necessary for contacting/recruiting schools, substantially more direct costs for printing and mailing of study materials to be distributed to many more schools, and greater effort in managing a sampling process with considerably more school replacement. The school-level incentive, then, must be seen ultimately as a cost-reduction tool used to help keep costs down, by reducing staff effort and direct printing, mailing, and related communications time and costs to recruit the necessary number of schools for the study.

While in the abstract, \$500 may seem to be an arbitrary amount, extensive experience, as noted above with other OMB-approved projects, dictates that it is at the equilibrium point between incentive effectiveness, and sampling and recruiting over-expenditures.

There is a real cost to the district and school administration for participating in this NIDA study. Offering a solid incentive increases school participation by providing some clear benefit to schools for this cost/benefit analysis, and helps keep overall project costs down.

Similarly, for the twins sample (600 participants), the \$10 incentive is necessary to remunerate the individuals for participation (average burden estimate is 51 minutes as described in Table 2a). Similarly given the administrative difficulty of recruiting this unique population (twins), an incentive reduces the overall project cost. The \$10 incentive (gift card) is fair and appropriate as it is closely approximates the minimum wage rate of \$7.25 (*Fair Labor Standards Act, US Department of Labor*) and the higher minimum wage rates established at the state level.

A.10 Assurance of Confidentiality Provided to Respondents

Assurances of confidentiality, to the extent provided by the law, will be grounded in the relevant regulations promulgated and monitored by the federal Office for Human Research Protections. Each institutional element of the R&D team and the data collection team has submitted and had approved a human subjects research protocol by its respective Institutional Review Board prior to the commencement of any work on the study. More specifically, the data collection team at BCSR has received full board protocol review approval from the Institutional Review Board at Rutgers, The State University of New Jersey; the CEDAR Center has received an approval from the Institutional Review Board at the University of Pittsburgh, and EXACT, has received a full board review approval from a private institutional review board, Chesapeake

Research Review, Inc., which has maintained full accreditation with the Association for the Accreditation of Human Research Protection Programs since 2004. Copies of the respective IRB approvals may be found as Attachment 1 (IRB approval notice for EXACT); Attachment 2 (IRB approval notice for CEDAR/Pittsburgh); and Attachment 3 (IRB approval notice for BCSR/Rutgers). A copy of the TLI Survey may be found as Attachment 4.

The language used on consent forms has been approved by and certified to these Institutional Review Boards. The law of the state in which a sampled school is situated will determine whether passive or active parental consent is required, and the respective Institutional Review Boards will contingently approve those consent forms. Please see Attachment 6 for the Parental Consent Form and corresponding Survey Fact sheet, and Attachment 7 for the TLI Web Survey Assent Page Text.

Data for this study is collected only in electronic format. Data collection through the TLI web survey application will automatically be entered into a file which only uses the unique identification number for the survey instance, but which is not identifiable to the individual respondent. The data will be stored on a secure password protected server location maintained by CEDAR. The nature of aggregate data analysis (as opposed to individual participant data analysis) further protects the confidentiality of any individual respondent; all data analyses are performed in the aggregate without reference to the survey instance identifiers. In addition, a NIDA application for a Certificate of Confidentiality has been submitted. A Privacy Impact Assessment will be conducted annually if the NIH Privacy Act office determines one is needed.

Records will be kept for 7 years, and only released to non-project person in accordance with the routine uses for disclosure identified in NIH SORN 09-25-0200.

A.11 Justification for Sensitive Questions

The nature of the study is to perfect an index for the reliable and valid protection of the propensity for substance abuse. It is necessary, then, to probe predictive cofactors for early-in-life drug and alcohol use and abuse. Thus, by definition, some survey questions will query attitudes and behaviors related to the psychological and sociological dimensions of such anti-social behaviors. All question responses are voluntary, however, and thus the risk of embarrassment or other negative consequence is greatly outweighed by the public health benefit of the TLI. In addition, only proven predictive indicators of substance abuse have been incorporated.³ As described above, the responses to these questions will be kept confidential to the extent permitted by law. These questions can be found in the Transmissible Liability Index survey, attachment 4.

Please note that while some of these questions seem duplicative, the TLI questions were evaluated and selected within the framework of computerized adaptive testing (CAT). CAT chooses the most appropriate questions to ask to a subject based on the previous answers.

Previous research on the instrument has shown that the CAT usually requires 18 out of 65 items

³ Kirisci, L., Tarter, R., Reynolds, M., Ridenour, T., Stone, C., & Vanyukov, M. (2012). *Computer adaptive testing of liability to addiction: Identifying individuals at risk*. Drug and Alcohol Dependence, Suppl. 1:S79-86. PMID: 22391133; Ridenour, T.A., Tarter, R.E., Kirisci, L., & Vanyukov, M.M. (2011). *Could a continuous measure of individual transmissible risk be useful in clinical assessment of substance use disorder?* Drug and Alcohol Dependence, 119, 10-17. PMID: 21715106; Kirisci, L., Tarter, R., Ridenour, T., Zhai, Z-W, Fishbein, D., Reynolds, M., & Vanyukov, M. (2013). *Age of alcohol and cannabis use onset mediates the association of transmissible risk in childhood and development of alcohol and cannabis disorders: evidence for common liability*. Experimental and Clinical Psychopharmacology, 2(11), 38-45. PMID: 23205723

to be answered. The original question list (before adapting it to CAT) was more extensive and included every variation of time (e.g. 6 months, 1 year).⁴ Through research we evaluated the most effective questions that would yield the least time commitment from a respondent. This resulted in a pool of 65 items for inclusion.

The probability of asking the same set of questions to the same person is very small. While there are similar items in the item pool, the odds of similar items being asked to the same person are limited. The CAT works by administering either more difficult or less difficult question based on the response, but not the same quality of item.

⁴ Vanyukov, M., Kirisci, L., Moss, L., Tarter, R., Reynolds, M., Maher, B., Kirillova, G., Ridenour, T., & Clark, D. (2009). *Measurement of the risk for substance use disorders. Phenotypic and genetic analysis of an index of common liability*. *Behavior Genetics*, 39, 233-244. PMID: 19377872.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

Table 2a: Estimated Annualized Burden Hours (Participants)

| Type of Respondent: Individuals and Households | Number of Respondents | Responses per Respondent | Average Burden Per Response (in hours) | Annual Hour Burden |
|--|----------------------------------|---|---|-------------------------------|
| Parent of 14-17 year-old students: Parent Consent Form Survey Fact Sheet | 5,000 | 1 | 5/60 | 417 |
| 14-18 year-old students: School Survey Transmissible Liability Index | | 1 | 30/60 | 2,500 |
| 14-18 year-old youths or their parents (Twins): Parental or Adult Consent Form | 600 | 1 | 5/60 | 50 |
| 14-18 year-old youths (Twins): Twin Type and Drug Alcohol Screening Survey | | 1 | 10/60 | 100 |
| 14-18 year-old youths (Twins): Dysregulation Inventory | | 1 | 10/60 | 100 |
| 14-18 year-old youths (Twins): Transmissible Liability Index | | 1 | 30/60 | 300 |
| Total | 5,600 | | | 3,467 |

Table 2b: Estimated Annualized Burden Hours (Non-Participants)

| Type of Respondent: Individuals and Households | Number of Respondents | Responses per Respondent | Average Burden Per Response (in hours) | Annual Hour Burden |
|---|----------------------------------|---|---|-------------------------------|
| School Consent Form + Survey Fact Sheet | 2,143 | 1 | 5/60 | 179 |

| | | | | |
|--------------------|------|---|------|-----|
| Twins Consent Form | 257 | 1 | 5/60 | 21 |
| Total | 2400 | | | 200 |

Based on BCSR’s experience conducting the CDC-sponsored Youth Risk Behavior Survey for the New Jersey Department of Education, it is estimated that the student level response rate will fall in the 70% to 75% range. Accordingly, table 2b above illustrates the burden for the non-participating respondents, estimated at 30% of the anticipated recruitment. Because the respondents for the school survey are all students between the ages of 14 through 18 who will be taking the TLI survey during regular school hours, there are no foregone earnings to respondents or record keepers. Because the respondents for the twins surveys are all teenagers between the ages of 14 through 18, if one were to assume that teenagers valued their time at the current minimum wage, the total cost to those respondents (participant & non-participant) would be the 571 hours x \$7.25 (*Fair Labor Standards Act, US Department of Labor*) or \$4,140, as shown below. As noted in A.1, other than 18 year old high school students or twins, there are no “adult” survey respondents.

Table 2c: Annualized Cost to Respondents

| Type of Respondent and Instrument | Estimated Number of Respondents | Frequency of Response | Average Time Per Respondent | Annual Hour Burden | Hourly Wage Rate | Respondent Cost |
|-----------------------------------|---------------------------------|-----------------------|-----------------------------|--------------------|------------------|-----------------|
| School Survey + consent form | 5,000 | 1 | 35 | 2,917 | n/a | \$0.00 |

| | | | | | | |
|---|------|---|----|-----|--------|---------|
| (participants) | | | | | | |
| School Consent Form (non-participants) | 2143 | 1 | 5 | 179 | n/a | \$0.00 |
| Twins Validity Survey + consent form | 600 | 1 | 55 | 550 | \$7.25 | \$3,988 |
| Twins Consent Form (non-participants) | 257 | 1 | 5 | 21 | \$7.25 | \$152 |

Table 2d shows the expected burden to school during the recruitment and survey administration periods. We anticipate contacting 120 schools, of which 36 are expected to participate. The anticipated time for a non-participating school to review the recruitment package and decline participation is 30 minutes. The anticipated time for a participating school to review the recruitment package and decide to participate is 30 minutes, which, when aggregated with an approximately 2.5 hour aggregate time for pre-administration, survey administration and post-administration activities. Thus, the anticipated total time for participating schools is 3 hours.

Table 2d: Estimated Annualized Burden Hours to Schools

| Type of Respondent and Instrument | Number of Respondents | Responses per Respondent | Average Time Per Respondent | Annual Hour Burden |
|--|-----------------------|--------------------------|-----------------------------|--------------------|
| Non-participating schools: recruitment packet | 84 | 1 | 30/60 | 42 |
| Participating schools: consent form, and survey administration | 36 | 1 | 180 | 6,480 |

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital, start-up, operational, or maintenance costs to the respondents in providing the information required by this research.

A.14 Annualized Cost to the Federal Government

The total contract value for this research is \$1,000,352 over the approximate 3 year performance period. Additionally, NIH incurs indirect overhead costs from the oversight of this project by a Health Science Administrator from the Division of Epidemiology, Services, and Prevention Research (National Institute on Drug Abuse), at the pay grade, 14 (GS) with a salary of \$130,000 (2013 data obtained from FedsDataCenter.com, which compiles public records released by the Office of Personnel Management and other agencies). With an estimated 5% of the annual full-time effort of this NIDA project officer, the cost is approximately \$6,500/annually. The below table summarizes the total and annualized (average) cost over a 3 year time period for both the contracted organization, EXACT Sport LLC ("EXACT") and its affiliated (sub-contractor) university partners, Rutgers University ("Rutgers") and University of Pittsburgh ("Pitt").

| | Year 1 | Year 2 | Year 3 | Total |
|--------------------------|-----------|-----------|-----------|-----------|
| Contract Cost | | | | |
| EXACT Cost (no fringe) | \$157,405 | \$157,405 | \$157,405 | \$472,215 |
| Pitt Cost w/o Fringe | \$97,579 | \$97,579 | \$97,579 | \$292,737 |
| Pitt Fringe (33.8% rate) | \$23,433 | \$23,433 | \$23,433 | \$70,298 |
| Rutgers Cost (no fringe) | \$55,034 | \$55,034 | \$55,034 | \$165,102 |

| | | | | |
|-------------------------------------|------------------|------------------|-----------------------|-------------------------|
| Total Contract Cost | \$333,451 | \$333,451 | \$33 3,451 | \$1,00 0,352 |
| NIH Oversight Cost | | | | |
| NIDA Officer (5%) | \$6,500 | \$6,500 | \$6,5 00 | \$19,5 00 |
| Contract Cost + NIH Cost | \$339,951 | \$339,951 | \$33 9,951 | \$1,01 9,852 |

A.15 Explanation for Program Changes or Adjustments

This is a new collection of information.

A.16 Plans for Tabulation and Publication and Project Time Schedule

1. Standardization of the TLI (School Survey)

Product: TLI outputs will be derived and displayed in two formats readily interpretable by practitioners; these formats are designed to be accessible even to those not specially trained in the interpretation of quantitative data. First, norms standardized to a population mean of 100 and standard deviation of 10 will be generated. The advantage of this metric is that it parallels the universally known scale in which the mean population IQ is 100; thus, there is an established familiarity with the meaning of the TLI score. Second, the TLI score will be recorded as a percentile. In this format, the practitioner receives information within a few seconds after a respondent's completion of the TLI survey; thus, predictive severity of risk will be ranked in

relation to the general population, making it instantly recognizable. The norms and all relevant supporting and descriptive information will be incorporated into the User Manual.

2. Psychometric Validation of the TLI (Twins)

Product: The output of the twins psychometric evaluation will document the TLI's construct validity by showing that heritability accounts for the majority of variance, concurrent validity by administering two versions of the instrument (full paper and pencil vs. CAT), and discriminative validity by comparing self-reported use of substances (i.e. Dysregulation D&A surveys) with TLI scores. Reliability will be examined over the two years of the study. As noted, the TLI measures transmissible risk for substance abuse disorder. The procedures and results of the analyses and all supporting information (e.g. sample, recruitment, etc.) will be incorporated into the User Manual.

3. Data Analysis: Logistic regression analyses will be deployed to predict the probability of the presence or absence of substance use disorder. Sensitivity, specificity, and overall classification accuracy will be determined using receiver operating characteristic (ROC) curve analysis.

4. Final Product: This study's research activities will conclude with preparation of the User Manual. That document will be made available in hard copy form, as well as electronically downloadable from EXACT's and CEDAR's websites. In addition, eCenter Research, a private health and social sciences research provider, has expressed interest in marketing the TLI under license from EXACT. The User Manual will include the following sections:

- i. literature review pertaining to transmissibility of substance abuse disorder;
- ii. review of measurement procedures for substance abuse disorder risk;
- iii. psychometric documentation of the TLI;
- iv. norms at ages 14, 15, 16, 17 and 18; and
- v. discussion of explanations and interpretations of TLI scores.

5. Timeline: After the OMB process is complete, the following steps will be taken:

| | Activity | Estimated Duration |
|---|---|--------------------|
| 1 | Standardization (n=5000) via school data collection study | 180 days |
| 2 | Construct validity analysis (n=600) via twins data collection / hereditary analysis | 60 days |
| 3 | Psychometric analysis using above data | 60 days |

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

NIH is not seeking approval to not display the OMB approval expiration date.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified in OMB Form 83-I, item 19, “Certification for Paperwork Reduction Act Submissions.”